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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,745

11/14/2005

Gustave Bergnes

09367.0085-00000

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06/11/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

06/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,745	Applicant(s) BERGNES ET AL.	
	Examiner TAMTHOM N. TRUONG	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3-18-08 (Election).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 14-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 13 is/are rejected.
- 7) ☒ Claim(s) 4-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/18/08, 11/14/05, 3/30/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse Group I in the response of 3-18-08 is acknowledged. Claims 1-27 are pending.

Claims 14-27 are withdrawn as being drawn to the non-elected material.

Only claims 1-13 are remained for consideration.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 1-3 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using compounds of formula I wherein R⁵ is **benzyl**, and R⁶ is an optionally substituted benzoyl, or optionally substituted **benzyl**, does not reasonably provide enablement for making and using compounds of formula I wherein R⁵ and R⁶ represent other moieties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims: The scopes of R⁵ and R⁶ cover many rings under the terms “aryl”, “aralkyl”, “heteroaryl” or “heteroaryl”, all of which can be further substituted with additional rings and functional groups. Thus, the scope of the compound of formula I is unduly broad and goes beyond the intended (pyrrolidyl (or piperidyl))-quinazoline.

The amount of direction or guidance presented: The specification provides a generic process for making compounds of formula I. Although the generic scheme teaches how an acyl group can be added to the ring having U-V, specific starting materials for various intended rings are not disclosed.

With working examples limited to R⁵ as benzyl and R⁶ as benzyl or benzoyl, the skilled chemist would not be able to make compounds of formula I with other choices of R⁵ and R⁶ and there has not been provided guidance that can be extrapolated from the prior art or the limited examples of the specification to direct the skilled artisan how to make and use the moieties that have not been prepared by the synthetic procedures of the instant specification. Furthermore, the

established biological activity for the species made cannot be extrapolated to other compounds of formula I due to the different structure attributed to R⁵ and R⁶. Thus, the specification fails to provide adequate guidance for making and using the claimed compounds with various rings or ring systems represented by R⁵ and R⁶.

The state of the prior art: There is no reference with analogous quinazolinone compounds where the second position is substituted with a pyrrolidinyl or piperidinyl. Thus, the state of the art does not support the broad scope of the instant formula I.

The relative skill of those in the art: Even with the advanced training, the skilled clinician would have to carry out extensive research to select an effective compound from the large Markush group of formula I. Not only one has to determine an IC₅₀ value, but also *in-vivo* activity to establish an LD₅₀, therapeutic index and pharmacokinetic profile for each compound. Given a large Markush group of the claimed formula I, such a task would require a tremendous amount of effort, time and resource.

The predictability or unpredictability of the art & The quantity of experimentation necessary: The pharmaceutical art has been known for its unpredictability due to various conflicting path ways, or biological factors that are sometimes genetically unique to individuals. In the instant case, the specification has not shown how a compound of formula I could be extensively substituted with complicated rings or ring systems and functional groups represented by R⁵ and R⁶ much less establishing activity for such a compound.

Thus, given the unpredictable nature of the art, and the vast number of compounds claimed herein, one skilled in the art will have to carry out undue experimentation to make and use compounds of formula I as recited in the above claims.

Claim Objections

2. Claims 4-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 4-12 are objected to because they recite compounds with R⁵ and R⁶ fully supported by the specification, and not taught or fairly suggested by the prior art of record.

Information Disclosure Statement

3. The IDS of 3-30-05 and 11-14-05 provide an extensive list of references. Applicant is reminded to bring to the examiner's attention the most relevant reference from such an extensive list. See the following excerpt from M.P.E.P 2004:

13. It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F. Supp. 948, 175 USPQ 260 (S.D. Fla. 1972), *aff'd*, 479 F.2d 1338, 178 USPQ 577 (5th Cir. 1973), *cert. denied*, 414 U.S. 874 (1974). But cf. *Molins PLC v. Textron Inc.*, 48 F.3d 1172, 33 USPQ2d 1823 (Fed. Cir. 1995).

Also, on the IDS of 3-30-05, the entry #116 has an improper citation because it lacks a date.

Art Unit: 1624

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**

***Tamthom N. Truong
Examiner
Art Unit 1624***

6-5-08